



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,338	09/29/2005	Liam Grover	10557/314216	8993
30559 7590 09/19/2007 CHIEF PATENT COUNSEL SMITH & NEPHEW, INC. 1450 BROOKS ROAD MEMPHIS, TN 38116			EXAMINER HEVEY, JOHN A	
			ART UNIT 1709	PAPER NUMBER
			MAIL DATE 09/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,338

Applicant(s)

GROVER ET AL.

Examiner

John A. Hevey

Art Unit

1709

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/2006 and 4/2007.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Status of Application

The claims 1-23 are pending and presented for examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. GB03/04197, filed on 09/26/2003.

Information Disclosure Statement (IDS)

The information disclosure statement (IDS) was submitted on 07/31/2006 and additionally on 04/17/2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Mandai et al. (US5342441).

In regards to claim 1-3, and 5, Mandai teaches a biocompatible hardenable material comprising a powder component containing $\text{Ca}_4\text{P}_2\text{O}_9$ (a source of calcium and pyrophosphate ions) and at least one of CaHPO_4 and

Art Unit: 1709

CaHPO₄-2H₂O, and a liquid component containing a secondary phosphate ion in a concentration of 1mM to 2 M and an organic acid ion in a concentration of 1mM to 2 M, wherein the weight ratio of the powder component to the liquid component is 0.5-4 (see claim 1).

In regards to claim 8, Mandai teaches where orthophosphoric acid is the source of secondary phosphate ions in said liquid component (see example 5, column 8).

In regards to claim 4, Mandai teaches where powder component, the main source of calcium, has a mean particle size of .1 to 50 micrometers (claim 4, column 20).

In regards to claim 6, Mandai teaches the use of TTCP, DCPD, HA, and others as a source of calcium (see table 3, column 9).

In regards to claim 7, Mandai teaches the use of a sodium hydrogen phosphate (see example 10, column 8).

In regards to claims 9-17, Mandai teaches various examples which if converted are assumed to possess water content between 0-90% and between 45-80% by weight, pyrophosphate ion source between 10-50% by weight, and orthophosphate ion source between 5-40% by weight (see tables 1-7).

In regards to claims 18-19, Mandai teaches the use of orthophosphates (see above), sodium citrates (see example 7), and chitosan (see column 4, lines 51-61).

Art Unit: 1709

3. Claims 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Chae et al (US6537589).

The instant claims require a cement composition comprising a calcium component and a liquid component comprising a solution of polyphosphate salt, wherein claim 23 further requires the use of sodium tripolyphosphate as said polyphosphate salt. Chae et al. teaches an artificial bone cement comprising tricalcium phosphate, monocalcium phosphate, and other additives in addition to a linear polyphosphate, wherein the polyphosphate has a chain length between 3 (tripolyphosphate) and 200 orthophosphate molecules (see claims 1 and 5).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mandai et al (US5342441) as applied above in view of Chae et al (US6537589).

Mandai teaches the bone cement as required by claim 1 (see 102 rejection above), and a process of kneading the material prior to setting (see column 13, lines 20-28). The process of kneading would inherently apply a pressure greater than 0 MPa, however Mandai does not provide the specific range of 0 to 100 MPa of pressure to the bone cement, but Chae et al. teaches

the application of 15 psi, equivalent to .10 MPa to a hardenable artificial bone material comprising beta-tricalcium phosphate and other phosphates. It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply pressure to the bone cement taught by Mandai, in order to mold or shape the cement material prior to application to a bone surface or other material. One would have been motivated to do so, in order to form a structurally sound body upon solidification of the cement and to benefit industrial applicability.

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chae et al (US6537589) as applied above in view of Constantz (US4880610).

The instant claim requires a bone cement composition of claim 21 wherein the calcium component is calcium hydroxide. Chae et al. teaches the bone cement composition as required by claim 21 (see 102 rejection above), but fails to teach calcium hydroxide as the source of calcium. However, Constantz teaches the use of calcium hydroxide as a source of calcium in a hardenable calcium phosphate material (column 4, lines 44-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bone cement as taught by Chae et al. with calcium hydroxide as taught by Constantz, because calcium hydroxide is a common source of calcium in the industry. One would have been motivated to make such a modification due to the anti-microbial effect of calcium hydroxide.

Art Unit: 1709

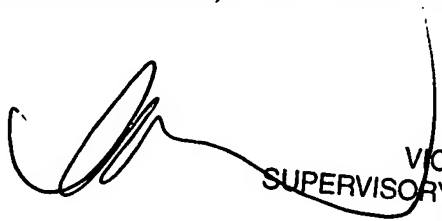
Conclusion

7. All claims are rejected.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John A. Hevey whose telephone number is 571-270-3594. The examiner can normally be reached on Monday - Friday 7:30 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on 571-270-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jah


VICKIE Y. KIM
SUPERVISORY PATENT EXAMINER